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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/978,274

10/15/2001

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9341-028-999

4439

7590

04/14/2006

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,274	Applicant(s) THOMAS ET AL.	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-55 and 57-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-51 and 53-55 and 57-67 is/are rejected.
- 7) ☐ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 01/20/06 in reply to the Office action of 08/12/05 has been entered. Claims 46-51, 53, 58-65 are amended are cancelled, and new claims 66-67 are added. Therefore, claims 46-55 and 57-67 are pending and are examined.

All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claim Rejections - 35 USC § 112

Claims 46-55 and 57-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-50, 59-60, and 63-65 are indefinite because it is unclear what is encompassed by "allowing natural development of a plant" or how to allow "natural development" of a plant. The specification does not clearly define what is encompassed by an inducible promoter that is cell-specific and induced during natural plant development. This rejection is repeated for the reasons of record as set forth in the last Office action of 08/12/05. In the response filed 01/20/06, Applicant has neither amended the claims nor argued against the rejection. Therefore, the rejection is maintained.

At claim 58, "a mature PAP-S protein", "a Pro-PAP-S", "a PAP-S α " and "a PAP-S β " imply that there are more than one Pro- PAP-S, more than one mature PAP-S

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protein, more than one Pro-PAP-S, more than one PAP-S α , and more than one PAP-S β . However, it is unclear if there is more than one of each of said PAP proteins.

Clarification is required to more clearly define the metes and bounds of the claim. In the response filed 01/20/06, Applicant has neither amended the claims nor argued against the rejection. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 46-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing nematode resistance in a transgenic plant by introducing a chimeric gene comprising the pokeweed antiviral protein (PAP) encoding sequences of SEQ ID NO: 1, 3, 5, or 7 under the control of a nematode inducible promoter in a transgenic plant, and plants and plant cells produced by said method, does not reasonably provide enablement for a method of inducing cell death in specific plant cells with any pokeweed encoding nucleic acids. This rejection is repeated for the reasons of record as set forth in the last Office action of 08/12/05.

Applicant's arguments filed 01/20/06 has been considered but are not deemed persuasive.

Applicant correctly states that the test for enablement is whether one reasonably skilled in the art could make and/or use the invention without undue experimentation based on the disclosure coupled with information known in the art at the time of filing. However, Applicant asserts that the claimed methods that employ any and all PAP encoding nucleic acid sequences including those that hybridize to the disclosed

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sequences are enabled. Applicant argues that the working examples disclosed in the specification demonstrate expression of Pro-PAP-S in both tobacco and potato plants at site that led to cell death in specific nematode feeding site (response, p. 10-11).

These are not found persuasive for the reasons of record. Both the prior art and Applicant's own working example provide the unpredictability inherent in transforming a plant with any nucleic acid encoding PAP to produce a healthy transformed plant with a desired pathogen resistance. Applicant's working example shows tobacco cells transformed with mature PAP-S encoding sequence under the control of an inducible promoter failed to produce transformed tobacco cells. The prior art teaches that transformation of a plant with a PAP encoding nucleic acids is highly unpredictable. For example, Lodge et al (PNAS, vol. 90, pp.7089-7093, 1993, Applicant's IDS) teach that the expression of PAP in transgenic plants may result undesired phenotype such as stunted, molted and sterility in the plant. Lodge et al teaches that tobacco plants expressing high levels (above 10ng/mg of protein) of wild type and mutant PAP tend to have stunted and mottled phenotype, and some the plants were sterile (see page 7090, Results and Discussion). On the other hand, Barbieri et al (Biochemica et Biophysica Acta, vol. 1154, pp. 237-282, 1993, Applicant's IDS) teaches that plant RIPs including PAP can act on their ribosome only at high levels of concentrations (see pages 251-252, section III-A). Another example is Tumer et al (PNAS, vol. 94, pp. 3866-3871, 1997, Applicant's IDS) who teach transgenic tobacco plants expressing high levels of PAP with point mutations showed growth reduction and lesions on their leaves (Fig. 3 on page 3868), while transgenic plants expressing high levels of active site mutant PAP

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didn't show antiviral activity, and while transgenic plants expressing low levels of C-terminal deletion mutant were resistant to virus and showed normal growth (Table 2, page 3870). Applicant has not provided evidence to support the broad scope of the claimed invention. A mere argument that the claimed invention is enabled without any convincing evidence is not probative.

Given that the broad scope of the claims encompassing a method that employs any and all nucleic acids encoding pokeweed antiviral protein and nucleic acids that hybridize to SEQ ID NO: 1, 3, 5, or 7 and encoding PAP having cell death inducing activity in a transgenic plant; the limited working examples; the unpredictability inherent in expressing PAP in a transgenic plant as evidenced by the multiple references cited in this action and in the last Office action; and the complex biological function of RIPs as discussed above and in the last Office action, the claimed invention is not enabled throughout the broad scope. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 66-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanieswski et al (6, 015, 940 (A)).

The claims are drawn to a molecule comprising a nucleic acid molecule encoding a mature PAP-S α or β , and a pathogen or chemical inducible promoter or cell-specific promoter that is induced during plant's natural development.

Kanieswski et al teach a construct comprising a DNA sequence encoding PAP-S protein and inducible promoter (columns 3, lines 2-10; column 4, lines 3-30; and claims

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5 and 13) for expressing in tissue-specific manner in cells where viral infection is known to occur. PAP-S inherently contains PAP-S α and β . Therefore, Kanieswski et al teach all claim limitations.

Remarks

Claim 52 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 64-65 would be allowable if the 112, 2nd rejection is obviated.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/4/06
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MEDINA A. IBRAHIM
PRIMARY EXAMINER

Medina A. Ibrahim